

**REMARKS/ARGUMENTS**

Claims 1-9, 106 and 107 are under examination.

*Rejection under 35 U.S.C. 112 should be withdrawn*

Claims 1-9, 106 and 107 are rejected under 35 USC § 112, first paragraph, as allegedly failing to comply with the enablement requirement. Applicant respectfully disagrees.

A decision on the issue of enablement requires determination of whether a person skilled in the pertinent art, using the knowledge available to such a person and the disclosure in the patent document, could make and use the invention without undue experimentation. **It is not fatal if some experimentation is needed, for the patent document is not intended as a production specification.** *Northern Telecom, Inc. v. DataPoint Corporation*, 908 F.2d 931 (Fed. Cir., 1990). As discussed in the previous response to the Office Action, the specification provides detailed disclosure for carrying out the claimed process. For example, pages 39 and 40 discloses exemplary statistical approaches to establish and test causal models for the genetic regulatory network. One of such statistic methods is cluster analysis. Cluster analysis, at the time of the filing, was well known to one skilled in the art of statistical analysis. The specification also incorporated several exemplary textbooks to teach how to perform cluster analysis. Building dynamic models of a network was also well known in the art of control theory (the specification cites Maybeck's classic textbook which discusses many ways to build dynamic models).

The specification teaches (page 40, line 14) that directional, correlational and causation models of gene regulation can be built based upon the level of expression of different genes. One method that was commonly used to build such models was path analysis. Path analysis was a well known technique for building models and was extensively used in, for example, psychology. Those skilled in the art were well versed in using multivariable data to establish and test models using path analysis.

The specification also provides another exemplary approach (page 40, lines 21), i.e., the LISREL. The specification teaches the benefits of this approach over path analysis. LISREL was a very well known technique that was implemented in many software packages with extensive documentations of how to use the software to analyze multivariable data (such gene expression profiles that include data about many genes in a large number of samples).

In addition, the specification also points to other causal models such as those described in Bentle, Rev. Psychol. 31:419-56 (1980) which is incorporated by reference. The Bentle review article examines various approaches and provides extensive citations. It also demonstrates the state of the art as early as in 1980, i.e., methods for establishing causal or other models using multivariate data set were well known.

The Examiner alleges that "it is the absence of specified parameters and assumptions for the general LISREL approach that fails to enable the claimed method." The Examiner points to Joreskog et al. with regard to measurement properties of observed variables and the causal effects and the unexplained variables. In response, Applicant respectfully submits that as taught in the specification, LISREAL is a **GENERAL APPROACH**, very little experimentation is required to generate a useful

analysis. One may prefer to adjust parameters to perfect the model to achieve REFINEMENT, but that is not required by the claim limitations. Enablement does not require an inventor to meet lofty standards of success in the commercial marketplace. Title 35 does not require that a patent disclosure enable one of skill in the art to make and use a perfected, commercially viable embodiment absent a claim limitation to that effect. *See, e.g., CFMT, Inc. v. Yieldup Int. Corp.*, 349 F.3d 1333 (Fed. Cir., 2003). Applicant also wants to point out that the specification is written for one of skill in the art who is skilled in both gene expression analysis and statistical model building and analysis. Even if one wants to adjust the models to perfect the analysis, the specification and the cited references provide ample guidance. For example, the cited references give numerous teachings and examples of how statistical models are analyzed to solve different problems. The specification clearly teaches the nature of gene expression monitoring data (multivariate multisample data sets) and the applicability of the multivariate statistical approaches to the data sets. Therefore, Applicant respectfully submit that the claims are enabled and this rejection under title 35 section 112 should be withdrawn.

### CONCLUSION

For these reasons, Applicants believe all pending claims are now in condition for allowance. If the Examiner has any questions pertaining to this application or feels that a telephone conference would in any way expedite the prosecution of the application, please do not hesitate to call the undersigned at (408) 731-5000.

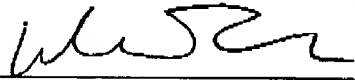
Application No.: 09/911,856

Docket No. 3424

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account 01-0431.

Applicants respectfully request that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

By 

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